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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,212	11/04/2003	Ingvar Olafsson	OLA03-002P	7114

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/702,212	OLAFSSON, INGVAR	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/4/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse Group I, claims 1-13 drawn to a composition for prophylaxis and treatment of inflammatory disease of the periodontum, comprising vitamin E, classified in class 514, subclass 458 by cancellation of claims 14-20 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treatment of inflammatory disease of the periodontum", does not reasonably provide enablement for the "**prophylaxis** of inflammatory disease of the periodontum". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a composition for **prophylaxis** and treatment of inflammatory disease of the periodontum, comprising vitamin E. The nature of the invention is extremely complex in that it encompasses the actual **prophylaxis** such that the subject treated with above compounds does not contract inflammatory disease of the periodontum

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass **prophylaxis** of inflammatory disease of the periodontum, comprising vitamin E which has potentially many different causes (i.e. many different bacterial organism or combination of bacterial organisms and immunological disorders). Each of which may or may not be addressed by the administration of the claimed compounds.

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed compounds to a subject in order to actually **prophylaxis** of inflammatory diseases of the periodontum is minimal. All of the guidance provided by the specification is directed towards **treatment** rather than **prophylaxis.**

Working Examples: All of the working examples provided by the specification are directed toward the treatment rather than **prophylaxis** of inflammatory disease of the periodontum.

State of the Art: While the state of the art is relatively high with regard to treatment of inflammatory disease of the periodontum, comprising vitamin E, the state of the art with regard to **prophylaxis** of inflammatory disease of the periodontum, comprising vitamin E of such disorders is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compounds was administered to a subject to **prophylaxis** of inflammatory disease of the periodontum.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual **prophylaxis** of inflammatory disease of the periodontum, comprising vitamin E in a human subject with the claimed compounds makes practicing the claimed invention unpredictable in terms of **prophylaxis** of inflammatory disease of the periodontum.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for the **prophylaxis** of inflammatory disease of the periodontum. If unsuccessful, which is likely given the lack of

significant guidance from the specification or prior art regard to the **prophylaxis** of inflammatory disease of the periodontum, with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding the **prophylaxis** of inflammatory disease of the periodontum, with any compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to **prophylaxis** the development of inflammatory disease of the periodontum, comprising administration of vitamin E.

Therefore, a composition for **prophylaxis** of inflammatory disease of the periodontum, comprising vitamin E is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 8 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Applicant's admission evidenced by Product Alert (1999).

Applicant admits that the vitamin E including a concentration of 28,000I.U.used was manufactured and distributed by Walgreen Co., located in Deerfield, IL 60015-4681 and sold under the trademark WALGREENS NATURE'S FINEST VITAMIN E SKIN OIL; and Colonial Dames Co. Ltd., located in Los Angeles, CA 90022-0022 and sold under the trademark COLONIAL DAMES VITAMIN E. (specification page 11, lines 15-20 and page 12, Example 1).

Applicants' recitation of an intended use for the prophylaxis and treatment of inflammatory disease of the periodontum does not represent a patentable limitation since such fails to impart any physical limitation to the same composition sold, manufactured and commercially available by Walgreens.

Product Alert reports that Colonial Natural dames pure oil-vitamin E manufactured by Colonial Dames is known in 1999. (text).

Claims 1, 3-6 and 8-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Walgreens.com (2002).

Walgreens.com commercializes natural vitamin E-oil 30000IU comprising D-alpha Tocopheryl Acetate.

Applicants' recitation of an intended use for the prophylaxis and treatment of inflammatory disease of the periodontum does not represent a patentable limitation since such fails to impart any physical limitation to the same composition sold, manufactured and commercially available by Walgreens.

Claims 1, 2 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Mendy (U.S.Patent No. 4,407,821).

Mendy teaches a composition comprising dl-alpha-tocopherol acetate used in dietetics, reanimation and therapeutics. (abstract, Examples 1, 9-12).

Applicants' recitation of an intended use for the prophylaxis and treatment of inflammatory disease of the periodontum does not represent a patentable limitation since such fails to impart any physical limitation to the same composition comprising same active agent taught by the cited prior art.

Claims 1, 4, 5, 7, 8, 10, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Drugstore.com (1999).

Drugstore.com reports Nourish Skin ™ Vitamin E Skin Oil is a moisturizing oil containing 56,000 IU of Vitamin E. (see pages 1 and 2).

Applicants' recitation of an intended use for the prophylaxis and treatment of inflammatory disease of the periodontum does not represent a patentable limitation

since such fails to impart any physical limitation to the same composition sold, manufactured and commercially available by General Nutrition.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102(a), (b).

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
January 21, 2005